K042703

OCT 12 2004

EXHIBIT 1

510(k) Summary

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

1. **Submitter's Identification:**

DXM Co., Ltd.
1016, Ilsantechnotown
Baeksuk-Dong, Ilsan-Gu,
Goyang-City
Republic of Korea 411-360
Telephone – 82 31 909-8275
Fax – 82 31 909-8276
Internet – http://www.dxm.co.kr
Contact – Lewis Baek

Date Summary Prepared: July 27, 2004

2. **Name of Device:**

Trade/Proprietary Name:

Cybird LED Curing LIght

Classification Name:

Activator, Ultraviolet, for Polymerization

Class in which Device has been placed:

The Dental devices panel has classified this device as Class II, 21 CFR Part 872.6070, Product Code EBZ.

3. Predicate Device Information:

Mini L.E.D by SATELEC (K032465)

4. Description and Intended Use:

Cybird by DXM Co., LTd is classified as an Ultraviolet Activator for polymerization(21 C.f.r.872.6070) because it is a device intended for the photo-polymerization light cured dental materials. The Cybird is a universal photo-polymerization light curing source working in cordless conditions and producing visible blue light in the 440 to 490nm waveband of spectrum with a power density comprised 1,000W/cm^2 , 11-8mm light-guide).These power densities are sufficient for the product intended uses ,namely, Photo-polymerization in the 440-490 nm waveband of visible light cured (VLC) dental materials , Photo – polymerization in the 440-490nm waveband of visible light cured(VLC) restorative composite materials, and Photo-polymerization in the 440-490 nm waveband of visible light cured (VLC) orthodontic brackets and orthodontic bonding and sealing materials.
Exposure times can be set for 5,10,15, or 20 seconds.

5. Substantial Equivalence:

The DXM Cybird L.E.D product has similar characteristics and intended uses as the 510(k) cleared light curing units ,the Satelec Mini L.E.D Mini L.E.D (K032465) for the photo-polymerization of dental materials, restorative composite materials ,and polymerization of bonding and sealing materials .
These devices are well established and determined to be safe and effective.

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing that was conducted in accordance with EN 60601-1: 1990 +A,+B; ,EN 60601-1-2: 2001; ,EN 61000-3-2:2000 and EN61000-3-3 , 1998/A1:2001 and EN 55011: 1998/A1:1999, Class B supports testing information demonstrating safety and effectiveness of the Cybird LED Curing Light in the intended environment of use.

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

7. Discussion of Clinical Tests Performed:

No clinical testing was conducted.

8. Conclusions:

The Cybird LED Curing Light is substantially similar to the predicate in intended use, operation, safety and function, and is safe and effective for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

DXM Company, LTD
C/O Ms. Carolann Kotula
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K042703
Trade/Device Names: Cybrid LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: September 29, 2004
Received: September 30, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

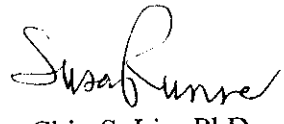
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K042703

Device Name: Cybird LED Curing LIght

Indications For Use:

The Cybird LED Curing Light is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 430-490 nm waveband of visible light.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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